MAY 0 7 2013

510(k) SUMMARY

AZURE Anterior Cervical Plate System

Submitter Information

Name:	Orthofix Inc.
Address:	3451 Plano Parkway Lewisville, TX 75056
Telephone Number:	214-937-2000
Fax Number:	214-937-3322
Email:	alisonbaduel@orthofix.com
Registration Number:	3008524126
Contac Person:	Ally Baduel Regulatory Affairs Specialist
Date Prepared:	March 22, 2012

Name of Device

Trade Name/Proprietary Name:	AZURE Anterior Cervical Plate System
Common Name:	anterior cervical plate system
Product Code:	KWQ - Appliance, Fixation, Spinal Intervertebral Body
Regulatory Classification:	Class II - 888.3060 – Spinal intervertebral body fixation orthosis
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Orthofix Anterior Cervical Plate System (K121658) & Hallmark Anterior Cervical Plate System (K050892 and K100614)
Reason for 510(k) Submission:	Device modification to cervical plates

Device Description

The AZURE Anterior Cervical Plate System is comprised of a variety of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) and Nitinol (per ASTM 2063) components that allow a surgeon to build a temporary anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation, which assists in the

surgical implantation of the devices. The instrumentation provided to facilitate implantation are Class I, manual orthopedic standard surgical instruments.

Intended Use / Indications for Use

The AZURE Anterior Cervical Plate System is a temporary implant, intended for anterior fixation to the cervical spine from C2 to C7 and indicated for:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spondylolisthesis;
c) Trauma (i.e., fracture or dislocation);
d) Spinal stenosis;
e) Deformities (i.e., scoliosis, kyphosis, and/or lordosis);
f) Tumor;
g) Pseudoarthrosis;
h) Revision of previous surgery

Summary of Technological Characteristics of the Device Compared to the Selected Predicate Devices

Characteristic	Subject Device	Predicates		
Device Name	AZURE Anterior Cervical Plate System	Orthofix Anterior Cervical Plate System (K121568)	Hallmark Anterior Cervical Plate System (K050892)	Hallmark Anterior Cervical Plate System (K100614)
Method of Fixation	ACP system intended for anterior fixation to the cervical spine from C2 to C7.	ACP system intended for anterior fixation to the cervical spine from C2 to C7.	ACP system intended for anterior fixation to the cervical spine from C2 to C7.	ACP system intended for anterior fixation to the cervical spine from C2 to C7.
Implantation	Anterior approach	Anterior approach	Anterior approach	Anterior approach
Design	Plates (1-level through 5-level)	Plates (1-level through 5-level)	Plates (1-level through 4-level)	Plates (5-level plate only)
Material	Ti6Al4V ELI per ASTM F136 and Nitinol per ASTM F2063.	Ti6Al4V ELI per ASTM F136 and Nitinol per ASTM F2063.	Ti6Al4V ELI per ASTM F136.	Ti6Al4V ELI per ASTM F136.

PERFORMANCE DATA-Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

Characteristic	Standard / Test/ FDA Guidance
Static Torsion Test	ASTM F1717-12
Static Axial Compression Bending Test	ASTM F1717-12
Dynamic Axial Compression Bending Test	ASTM F1717-12

Performance Data Summary
Mechanical testing for the subject AZURE Anterior Cervical Plate System was conducted in accordance to ASTM F1717-12- Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model. Test results demonstrated that the new, proposed device is substantially equivalent to the predicate device the Hallmark Anterior Cervical Plate System (K050892 and K100614) that have the same intended use, similar indications, technological characteristics, and principles of operation.

Basis of Substantial Equivalence
The subject AZURE Anterior Cervical Plate System is substantially equivalent in design, configuration, function, and indications for use to the Orthofix Anterior Cervical Plate System (K121658) and is substantially equivalent in design, configuration, function, performance and indications for use to the Hallmark Anterior Cervical Plate System (K050892 & K100614).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2013

Orthofix, Incorporated
% Ms. Ally Baduel
Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K130825
Trade/Device Name: AZURE Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 09, 2013
Received: April 10, 2013

Dear Ms. Baduel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130825

Device Name: AZURE Anterior Cervical Plate System

Indications for Use:

The AZURE Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7 and indicated for:

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g) Pseudoarthrosis;
h) Revision of previous surgery

Prescription Use: X (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices